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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,894	12/22/2004	Fukumi Morishige	122229	2882

25944 7590 10/15/2008

OLIFF & BERRIDGE, PLC
P.O. BOX 320850
ALEXANDRIA, VA 22320-4850

EXAMINER	
WANG, SHENGJUN	
ART UNIT	PAPER NUMBER
1617	
MAIL DATE	DELIVERY MODE
10/15/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,894	MORISHIGE, FUKUMI	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4 and 5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of applicants' amendments and remarks submitted July 1, 2008 is acknowledged.

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1, 4 and 5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to preventing virus infection broadly, and preventing SARS in particular by administering arginine and vitamin C.

The disclosure teaches that:

> The prevention of viral infection by such a vaccine is, however, not always universal. Viruses always change their structures to yield new strains. A vaccine efficacious to a certain virus is not efficacious to a new strain of the virus which raised as a result of change in structure thereof. Among such viruses, RNA viruses severely change in their structures. There has been a report that coronavirus inducing SARS, for example, shows different nucleotide sequences between its strain in Hong Kong and that in Taiwan. Even if a vaccine efficacious for the prevention of SARS is developed, it may highly possibly become inefficacious immediately because of the rapid change in structure of the virus and is not promising. (0004).

Thus, preventing viral infection is very unpredictable and only known method for preventing virus infection is vaccination.

The disclosure assert that arginine is useful for enhancing immune function [0020], and vitamin C may useful for resolving fibrogenesis caused by viral infection. [0024]. The application provides no written description of factual bases supporting the assertion, and no rationale as how

and why the combination of the two agents would be effective for preventing viral infection in general, and preventing SARS in particular.

The two working examples (examples 1 and 2) are drawn to treatment of patient suffering pulmonary diseases, and showing nothing about preventing viral infection.

Since there is no known method for preventing viral infection by administering agents other than vaccine, and since the application fails to set forth any fact and/or rationale that all viral infection, including SARS, HIV, hepatitis C, can be prevented by the claimed method, and thereby accomplish a task that skilled artisans have been trying for years but without a success, a skilled artisan would have reasonable doubt that appellants have possession of a such method.

3. Claims 1, 4 and 5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

4. Attention is directed to In re Wands, 8 USPQ 2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factor to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art,

7) the predictability of the art, and

8) the breadth of the claims.

5. The claims are drawn to preventing virus infection generally, and preventing SARS in particular by administering arginine and vitamin C.

The state of prior art: the disclosure reveals that

> The prevention of viral infection by such a vaccine is, however, not always universal. Viruses always change their structures to yield new strains. A vaccine efficacious to a certain virus is not efficacious to a new strain of the virus which raised as a result of change in structure thereof. Among such viruses, RNA viruses severely change in their structures. There has been a report that coronavirus inducing SARS, for example, shows different nucleotide sequences between its strain in Hong Kong and that in Taiwan. Even if a vaccine efficacious for the prevention of SARS is developed, it may highly possibly become inefficacious immediately because of the rapid change in structure of the virus and is not promising. [0004].

Thus, preventing viral infection is very unpredictable and only known method for preventing virus infection is vaccination.

The disclosure assert that arginine is useful for enhancing immune function [0020], and vitamin C may useful for resolving fibrogenesis caused by viral infection. [0024]. The application provides no written description of factual bases supporting the assertion, and no rationale as how and why the combination of the two agents would be effective for preventing viral infection in general, and preventing SARS in particular. Thus, the application fails to provide sufficient guidance and/or direction to a skilled artisan as how to accomplish prevention of viral infection.

The two working examples (examples 1 and 2) are drawn to treatment of patient suffering pulmonary diseases, and showing nothing about preventing viral infection. Thus, the application provides no working examples for preventing viral infection.

Therefore, the instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation.

Response to the Arguments

Applicants' amendments and remarks submitted July 1, 2008 have been fully considered, but are not persuasive.

Regarding the written description rejection, Applicants cites paragraphs [0011], [0012], [0015], [0016]. [0019], [0021] and [0028], for written description supporting the claimed invention. The examiner respectfully disagrees. Note the claimed invention is drawn to "A method for preventing infection of a virus in general, and SARS virus in particular, comprising administering arginine and a high dose of vitamin C. paragraph [0011] merely provide a conclusive statement. There is no established evidence that a free radical would be effective for preventing viral infection. [0012] alleges some biological functions of vitamin C, without any factual support. Further, there is no written description as how such alleged function would have been effective for preventing viral infection. [0015] and [0016] asserts an effective amount of vitamin C, with no written description showing that the asserted amount of vitamin C is effective for preventing viral infection. [0019] describes that arginine enhances immune systems activity. However, no written description shows such enhancements would be sufficient for preventing viral infection. In fact both vitamin C and arginine are known in the art for enhancing immune system (see the references cited in the prior office action). However, there is no evidence showing that such enhancement is sufficient and effective for preventing viral infection. [0006] merely shows that there are known small molecular compound for treating viral infection, not preventing viral infection.

Applicants' arguments regarding the enablement rejection are not tenable. As stated in the rejections, the application provide no working example for preventing viral infection, and no rationale as why the combination of vitamin C and arginine would be effective for preventing viral infection in general and SARS infection in particular. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed of physiological activity. The application merely gives conclusive statements and provides no evidence that vitamin C and arginine are effective for preventing viral infection.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shengjun Wang/
Primary Examiner, Art Unit 1617